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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/706,496 | 11/12/2003 | Benjamin Oshlack | 200.93311CON8 | 7218 |
| 20583 | 7590 | 09/17/2004 | EXAMINER | |
| JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017 | | | WEBMAN, EDWARD J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1617 | |

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
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8/16/04

DATE MAILED:

This is a communication from the examiner in charge of your application.
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OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 11/12/03

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 11, 12 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 11, 12 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 11/12/03
☐ Interview Summary, PTO-413
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldie et al in view of Zierenberg et al.

Goldie et al teach controlled release of hydromorphone (oxycodone) hydrochloride (title). Acrylic polymers are specified (column 2 line 56). Tablets are specified (column 2 line 40). 2-40mg drug is disclosed (column 2 line 43).

Zierenberg et al teach a delayed release tablet comprising an acrylic polymer and a second polymer such as polyvinylpyrrolidone to vary the rate of release (column 2 lines 46-48, column 2 line 67-column 3 line 8). Up to 50 mg of active is specified (column 3 lines 15-20). Compression is specified (column 4 line 10).

It would have been obvious to one of ordinary skill to add polyvinylpyrrolidone to the composition of Goldie et al to achieve the beneficial effect of varying the rate of release in view of Zierenberg et al.

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldie in view of Hill.

Goldie et al is discussed above.

Hill teach a controlled release tablet comprising a carboxy vinyl polymer and polymeric vinyl pyrrolidone (abstract). Compression is specified (column 2 line 43). A wide variety of medicaments is disclosed (column 2 line 54).

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It would have been obvious to one of ordinary skill to add polyvinylpyrrolidone to the composition of Goldie et al to achieve the additional effect of a second control release agent to the acrylic polymer of Goldie et al in view of Hill. In re Kerkhoven 626 F.2d 846 (CCPA 1980).

No claims allowed.

Any inquiry concerning this communication should be directed to Edward J. Webman at telephone number 571-272-0633.

Webman/tgd

August 18, 2004


EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500